K061925 page 1 of 2

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
Mini TightRope™ Repair Kit

OCT 3 1 2006

NAME OF SPONSOR:

Arthrex, Inc.
1370 Creekside Boulevard
Naples, Florida 34108-1945

510(K) CONTACT:

Sally Foust, RAC
Regulatory Affairs Project Manager
Telephone: (239) 643-5553 ext. 1251
FAX: (239) 598-5539

TRADE NAME:

Mini TightRope™ Repair Kit

COMMON NAME:

Button/Suture

DEVICE PRODUCT CODE/CLASSIFICATION:

HTN: Single/multiple component metallic bone fixation appliances and accessories:
21 CFR 888.3030

PREDICATE DEVICES
K041189: TRIM-IT Family (Arthrex, Inc.)
K052776: TightRope AC Device (Arthrex, Inc.)
K043248: TightRope Syndesmosis Device (Arthrex, Inc.)

DEVICE DESCRIPTION AND INTENDED USE
The Mini TightRope™ Repair Kit is designed as two differently sized metal buttons and FiberWire™ suture. The buttons are pre-threaded with FiberWire suture, looped twice through the buttonholes. A pull-through FiberWire suture is looped through one button.

The Mini TightRope™ Kit is intended as an adjunct in fracture repair involving metaphyseal and periarticular small bone fragments where screws are not indicated, and as an adjunct in external and intramedullary fixation systems involving plates and rods, with fracture braces and casting.

Specifically, the Arthrex Mini TightRope Repair Kit is intended to provide fixation during the healing process following:

1) Syndesmotic trauma, such as fixation of dorsal distal radioulnar ligament (DRUL) disruptions;
2) Tarasometatarsal (TMT) injury, such as fixation of foot soft tissue separations due to a Lisfranc injury (Midfoot Reconstruction); and
3) Hallux Valgus reconstruction (correction) by providing for the reduction of 1st metatarsal – 2nd metatarsal intermetatarsal angle.

SUBSTANTIALLY EQUIVALENCE

Arthrex has determined that the Mini TightRope™ Repair Kit is substantially equivalent to the predicate devices where basic features and intended uses are the same. Any design differences between the Arthrex Mini TightRope™ Repair Kit when compared to predicate devices used in the standard medical practice for the treatment of DRUL disruptions in syndesmotic trauma, TMT (Lisfranc) injuries, and reduction for the 1st metatarsal – 2nd metatarsal intermetatarsal angle following Hallux Valgus reconstruction (correction) are considered minor and do not raise any questions concerning safety and effectiveness. Any differences have been found to have no apparent effect on the performance, function, or intended use of the device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Arthrex, Inc.
% Ms. Sally Foust, RAC
Regulatory Affairs Project Manager
1370 Creekside Boulevard
Naples, Florida 34108

OCT 3 1 2006

Re: K061925
Trade/Device Name: Mini TightRope™ Repair Kit
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/multiple component metallic bone fixation appliances and accessories
Regulatory Class: Class II
Product Code: HTN
Dated: September 27, 2006
Received: September 28, 2006

Dear Ms. Foust:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

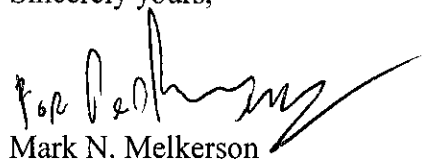
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or 240-276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K061925

Device Name Mini TightRope™ Repair Kit

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Prescription Use __X____ AND/OR Over-The-Counter Use ___No
(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative,
and Neurological Devices

510(k) K061925